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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Robin D. Pierce

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EXAMINER

OLSEN, KAJ K

ART UNIT

PAPER NUMBER

1795

MAIL DATE

DELIVERY MODE

02/02/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/674,695	Applicant(s) PIERCE ET AL.	
	Examiner KAJ K. OLSEN	Art Unit 1795	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,6-16,18 and 21-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,6-16,18 and 21-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Response to Appeal

1. In view of the appeal filed on 11/07/2008 and the new art the examiner is including herein, PROSECUTION IS HEREBY REOPENED. A new ground of rejection is set forth below.

To avoid abandonment of the application, applicant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then applicant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

/Nam X Nguyen/

Supervisory Patent Examiner, Art Unit 1753.

Claim Rejections - 35 USC § 103

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1, 3, 6-11, 29, 31, 32, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Say et al (USP 6,103,033) in view of Mizutani et al (Bull. Chem. Soc. Jpn., 64, 1991, pp. 2849-2851) and/or Saby et al (Analytica Chimica Acta, 304, 1995, pp. 33-39). Mizutani and Saby are being cited and relied on for the first time with this office action.

4. Say discloses a biosensor for determining a concentration of an analyte in a liquid sample (e.g. glucose in blood) comprising an electrode support 50, an arrangement of electrodes (58, 60, 62) disposed on the electrode support, the arrangement of electrodes comprising at least one working electrode 58 and a second electrode (60, 62), the working electrode comprising conductive ink and at least one enzyme and mediator in it. See col. 20, ll. 10-29 where Say teaches placing the catalyst in the electrode ink and see col. 19, l. 43 - col. 20, l. 9 where Say considers the mediator to be part of the catalyst as well. Say discloses first and second conductive tracks 52 leading from the working and second electrode to an electrical contact 49. See fig. 11 for example. Say does not explicitly disclose the use of a polymer that provides a hydrophilic domain. Mizutani teaches that enzymes such as glucose oxidase (GOD) can lose their activity when incorporated into a hydrophobic carbon electrode, and teaches that combining the enzyme with a polymer such as polyethylene glycol (PEG) improves the activity of the enzyme. See fig. 2 and 3 and p. 2850. With respect to PEG creating hydrophilic domains, the present invention evidences that PEG is a hydrophilic polymer (claims 32 and 34 for example).

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Moreover, Mizutani teaches that the PEG-GOD complex is soluble in aqueous media (Results and Discussion on p. 2849). Saby further teaches that the PEG prevents the enzyme from denaturing in the carbon electrode (p. 34, par. 2). This reason is precisely analogous to the present invention's reason for adding the PEG hydrophilic domains, namely to provide a medium where the structure of the enzyme is not altered (p. 5, ll. 13-15). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of either Mizutani and/or Saby for the biosensor of Say so as to improve the activity of the enzyme in the conductive ink by allowing it to better dissolve into or to prevent it from denaturing in the carbon based ink of Say (col. 9, ll. 32-36).

5. With respect to the mediator composition, the osmium complexes of col. 19, ll. 12-33 for example read on the defined organometallic and organic compounds of the claims.
6. With respect to the use of small sample volumes, see Say, col. 4, ll. 8-14.
7. With respect to the electrode spacing, see Say col. 11, ll. 22-36.
8. With respect to the electrode area, it would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize electrode areas of from 0.5 mm² to 5 mm², since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. In particular, larger electrodes would provide greater sensitivity while smaller electrodes would hold the overall size of the sensor down. Finding the appropriate area that balances these competing concerns requires only routine skill in the art.
9. With respect to the presence of a third or trigger electrode, Say discloses a third electrode 62 (col. 14, ll. 44-50) and this would read on the defined third electrode. Although not disclosed

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as being a trigger electrode, the term “trigger” merely defines how applicant intends to utilize the electrode and does not further define the structure of the electrode itself.

10. With respect to the set forth fourth electrode, see Say fig. 6 and col. 14, ll. 29-43. With respect to the electrode having a trigger function, this again defines how the electrode is to be used and doesn't further define the structure of the electrode itself.

11. With respect to the use of dehydrogenase, see Say col. 19, ll. 43-55.

12. With respect to claim 31 (those limitations not covered above), Say discloses that the biosensor can be made to contact a meter (i.e. control unit). See col. 13, ll. 28-40.

13. Claims 1, 3, 6-11, 29, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Say et al (USP 6,103,033) in view of Charlton et al (USP 5,798,031).

14. Say discloses a biosensor for determining a concentration of an analyte in a liquid sample (e.g. glucose in blood) comprising an electrode support 50, an arrangement of electrodes (58, 60, 62) disposed on the electrode support, the arrangement of electrodes comprising at least one working electrode 58 and a second electrode (60, 62), the working electrode comprising conductive ink and at least one enzyme and mediator in it. See col. 20, ll. 10-29 where Say teaches placing the catalyst in the electrode ink and see col. 19, l. 43 - col. 20, l. 9 where Say considers the mediator to be part of the catalyst as well. Say discloses first and second conductive tracks 52 leading from the working and second electrode to an electrical contact 49. See fig. 11 for example. Say does not explicitly disclose the use of a polymer that provides a hydrophilic domain. Charlton discloses that the enzyme can be deposited down onto an electrode in the presence of a hydrophilic polymer, which would increase the hydration access to the enzyme itself. See col. 1, ll. 51-59 and col. 2, ll. 58-60. It would have been obvious to one

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of ordinary skill in the art at the time the invention was being made to utilize the teaching of Charlton for the sensor of Say so as to increase the hydration properties of the electrode thereby permit adequate sample exposure to the enzyme. The addition of a hydrophilic polymer to the conductive ink of Say would inherently create hydrophilic domains in the conductive ink.

15. With respect to the various dependent claims here, see the discussion of Say above.

16. Claims 1, 3, 6-16, 18 and 21-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Feldman in view of Say and either Mizutani and/or Saby.

17. Feldman discloses a biosensor (col. 1, ll. 13-14) having: an electrode support (col. 26, ll. 25-26 and Fig. 2, 38); an arrangement of electrodes disposed on the electrode support, the arrangement of electrodes comprising at least a working electrode and at least a second electrode (col. 26, ll. 22-23 and Fig. 2, 22 and 24); a first conductive track leading from the working electrode to an electrical contact associated with the working electrode and a second conductive track leading from the second electrode to an electrical contact associated with the at least second electrode (Fig. 2, 22 and 24); and at least one reagent incorporated in the working electrode (col. 21, ll. 28-31) comprising an enzyme (col. 24, ll. 18-43) and a mediator (col. 15, ll. 20- col. 24, ll. 15). Specifically, the enzyme can comprise glucose oxidase or dehydrogenase (col. 24, ll. 27-28) and the mediator can comprise ferrocene (col. 15, ll. 32), quinones (col. 20, l. 50-col. 21, l. 15), ferricyanide (col. 22, l. 28) or ruthenium bipyridyl complexes (col. 15, ll. 33-38). Feldman does not disclose placing the enzyme and the mediator into a conductive ink. Say (who has the same assignee as Feldman) discloses that in an effort to minimize leaching of the catalysts (i.e. the enzyme and mediator), the catalysts can be incorporated directly into the conductive ink of the sensor. See col. 19, l. 56 - col. 20, l. 29, especially col. 20, ll. 10-29. It

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would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Say for the biosensor of Feldman so as to obviate the need for multiple coating steps for the electrode as well as keeping the enzyme from leaching away. Keeping the mediator and enzyme from leaching away was a particular concern of Feldman (see abstract for example) and the suggestion of incorporating the enzyme and mediator into the conductive ink by Say represents an alternate or additional way to prevent such a leaching from occurring.

18. Neither Feldman nor Say explicitly disclose the use of a polymer that provides hydrophilic domains in the conductive ink. Mizutani teaches that enzymes such as glucose oxidase (GOD) can lose their activity when incorporated into a hydrophobic carbon electrode, and teaches that combining the enzyme with a polymer such as polyethylene glycol (PEG) improves the activity of the enzyme. See fig. 2 and 3 and p. 2850. With respect to PEG creating hydrophilic domains, the present invention evidences that PEG is a hydrophilic polymer (claims 32-34 for example). Moreover, Mizutani teaches that the PEG-GOD complex is soluble in aqueous media (Results and Discussion on p. 2849). Saby further teaches that the PEG prevents the enzyme from denaturing in the carbon electrode (p. 34, par. 2). This reason is precisely analogous to the present invention's reason for adding the PEG hydrophilic domains, namely to provide a medium where the structure of the enzyme is not altered (p. 5, ll. 13-15). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of either Mizutani and/or Saby for the biosensor of Feldman and Say so as to improve the activity of the enzyme in the conductive ink by allowing it to better dissolve into or to prevent it from denaturing in the carbon based ink of Say (col. 9, ll. 32-36).

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19. With respect to the choice of mediator, see Feldman col. 15, ll. 20-25.
20. With respect to the use of a low volume, see Feldman col. 7, ll. 52-55.
21. With respect to the electrode spacing and area, see Feldman col. 24, ll. 66 and 67; col. 25, ll. 1-3; and col. 49, ll. 7 and 8.
22. With respect to the presence of a trigger electrode, Feldman discloses a biosensor wherein the electrode arrangement further comprises a trigger electrode (col. 50, ll. 60 and 61 and col. 51, ll. 1-12). Applicant discloses that a trigger electrode can be used to determine when the sample has been applied to the strip, thereby activating the assay protocol (p. 10, ll. 19-21). The trigger electrode prevents the assay from beginning until an adequate quantity of sample has filled the reaction zone (p. 10, ll. 22-24). Feldman discloses a sensor including a fill indicator, such as an indicator electrode, that can be used to determine when the measurement zone or sample chamber has been filled (col. 2, ll. 64-67). An indicator electrode is defined as one or more electrodes that detect partial or complete filling of a sample chamber and/or measurement zone (col. 7, ll. 3-5). Therefore, Feldman's indicator electrode is interpreted to be synonymous with trigger electrode.
23. With respect to the presence of a third and fourth electrode, see Feldman col. 49, ll. 19-21 and col. 51, ll. 37-45.
24. With respect to the set forth insulating layer, see Feldman col. 8, ll. 23-29 and fig. 4, element 40.
25. With respect to the set forth layer of mesh, see Feldman col. 29, ll. 47-54.
26. With respect to the set forth capillary, see Feldman col. 26, ll. 58-67 or fig. 5, element 26.
27. With respect to the set forth layer of tape, see fig. 2, element 30.

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28. With respect to claims 16, 18, and 21-30 (those limitations not previously covered above), Feldman discloses a first substrate having two major surfaces (fig. 1, element 38 or fig. 3, element 38); a second substrate having two major surfaces (fig. 1, element 38 or fig. 3, element 38); where the working electrode is disposed on one major surface of the first substrate (col. 3, ll. 18 and 19, fig. 1, element 22 or fig. 3, element 22) while a second electrode is disposed on one major surface of the second substrate (col. 3, ll. 19 and 20, fig. 1, element 24 or fig. 3, element 24). Feldman further discloses an insulating layer disposed between said working electrode and said at least second electrode (col. 8, ll. 3-29, fig. 1, element 28 or fig. 3, element 28).

29. With respect to method claim 31 (those limitations not previously covered), Feldman teaches the use of a meter that contacts the leads of the sensor. See col. 35, ll. 27-61.

30. Claims 1, 3, 6-16, 18 and 21-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Feldman in view of Say and Charlton.

31. Feldman discloses a biosensor (col. 1, ll. 13-14) having: an electrode support (col. 26, ll. 25-26 and Fig. 2, 38); an arrangement of electrodes disposed on the electrode support, the arrangement of electrodes comprising at least a working electrode and at least a second electrode (col. 26, ll. 22-23 and Fig. 2, 22 and 24); a first conductive track leading from the working electrode to an electrical contact associated with the working electrode and a second conductive track leading from the second electrode to an electrical contact associated with the at least second electrode (Fig. 2, 22 and 24); and at least one reagent incorporated in the working electrode (col. 21, ll. 28-31) comprising an enzyme (col. 24, ll. 18-43) and a mediator (col. 15, ll. 20- col. 24, ll. 15). Specifically, the enzyme can comprise glucose oxidase or dehydrogenase

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(col. 24, ll. 27-28) and the mediator can comprise ferrocene (col. 15, ll. 32), quinones (col. 20, l. 50-col. 21, l. 15), ferricyanide (col. 22, l. 28) or ruthenium bipyridyl complexes (col. 15, ll. 33-38). Feldman does not disclose placing the enzyme and the mediator into a conductive ink. Say (who has the same assignee as Feldman) discloses that in an effort to minimize leaching of the catalysts (i.e. the enzyme and mediator), the catalysts can be incorporated directly into the conductive ink of the sensor. See col. 19, l. 56 - col. 20, l. 29, especially col. 20, ll. 10-29. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Say for the biosensor of Feldman so as to obviate the need for multiple coating steps for the electrode as well as keeping the enzyme from leaching away. Keeping the mediator and enzyme from leaching away was a particular concern of Feldman (see abstract for example) and the suggestion of incorporating the enzyme and mediator into the conductive ink by Say represents an alternate or additional way to prevent such a leaching from occurring.

32. Neither Feldman nor Say explicitly disclose the use of a polymer that provides hydrophilic domains in the conductive ink, Charlton discloses that the enzyme can be deposited down onto an electrode in the presence of a hydrophilic polymer, which would increase the hydration access to the enzyme itself. See col. 1, ll. 51-59 and col. 2, ll. 58-60. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Charlton for the sensor of Feldman and Say so as to increase the hydration properties of the electrode thereby permit adequate sample exposure to the enzyme. The addition of a hydrophilic polymer to the conductive ink of Feldman and Say would inherently create hydrophilic domains in the conductive ink.

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33. With respect to the various dependent claims, see the discussion of Feldman and Say above.

34. Claims 32 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Say in view of Charlton as set forth for claims 1 and 31 above, and in further view of Yamashita et al (USP 5,472,590).

35. Say and Charlton set forth all the limitations of claims 32 and 34, but did not explicitly recite the use of polyethylene glycol as the hydrophilic polymer. However, polyethylene glycol is a subset of the broader polymer class of polyethylene oxide utilized by Charlton. In particular, polyethylene glycol is polyethylene oxide where the terminal groups of the polymer are hydroxyl units. Yamashita explicitly teaches that polyethylene glycol is a particular useful choice of polyalkylene oxide polymer when the property being desired is a hydratable substance (i.e. “water-keeping property”). See abstract and col. 5, ll. 51-63 of Yamashita. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the polyethylene glycol as taught by Yamashita for the polyethylene oxide suggested by Charlton for the biosensor of Say and Charlton because polyethylene glycol has been demonstrated as being a suitable choice of hydratable polyethylene oxide for sensor applications.

36. Claims 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Feldman in view of Say and Charlton as set forth for claims 1, 16, and 31 above, and in further view of Yamashita.

37. The references set forth all the limitations of claims 32-34, but did not explicitly recite the use of polyethylene glycol as the hydrophilic polymer. However, polyethylene glycol is a subset of the broader polymer class of polyethylene oxide utilized by Charlton. In particular,

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polyethylene glycol is polyethylene oxide where the terminal groups of the polymer are hydroxyl units. Yamashita explicitly teaches that polyethylene glycol is a particular useful choice of polyalkylene oxide polymer when the property being desired is a hydratable substance (i.e. “water-keeping property”). See abstract and col. 5, ll. 51-63 of Yamashita. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the polyethylene glycol as taught by Yamashita for the polyethylene oxide suggested by Charlton for the biosensor of Feldman, Say, and Charlton because polyethylene glycol has been demonstrated as being a suitable choice of hydratable polyethylene oxide for sensor applications.

Response to Arguments

38. Applicant's arguments filed in the Appeal Brief of 11/7/2008 have been fully considered but they are not persuasive.

39. Applicant urges Charlton does not teach that a hydrophilic polymer can be incorporated into the conductive ink. This argument as well as most of the arguments that follow ignore that the rejection is not based on Charlton in isolation, but rather is based on Say in view of Charlton and what the combination of the two references would suggest to one possessing ordinary skill in the art. In particular, Charlton teaches that it is desirable to have the oxidoreductase enzyme and the electron acceptor (i.e. mediator) of the sensor be distributed with a hydrophilic polymer to promote hydration of the enzyme (col. 1, ll. 48-59 and col. 2, ll. 58-60). Later, Charlton explicitly urges that this agent to induce wicking of the blood could be “included in the chemistry layer” (col. 4, ll. 10 and 11). The chemistry layer would be a layer containing the enzyme and mediator. In Say, the chemistry layer disclosed in the embodiment of col. 20 is in

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the conductive ink. Hence, if it is desirable to improve the hydration properties of the enzyme by combining the enzyme with a hydrophilic polymer and including that layer in the actual chemistry layer of the sensor (as Charlton suggests), then it would have been obvious to include that hydrophilic polymer in the chemistry layer (i.e. conductive ink) of Say. Applicant's continual emphasis on the fact that Charlton only disclosed placing the hydrophilic polymer in a separate sensing layer over the conductive track ignores the fact that Say already recognized that the sensing components (i.e. the chemistry components) can either be utilized as a separate sensing layer 64 over the conductive track (like Charlton) or that these components of the sensing layer can be incorporated into the actual conductive ink itself. Compare Say fig. 3A and col. 6, ll. 25-42 with col. 20, ll. 10-29. If it would have been obvious to add a hydrophilic polymer to the sensing layer of a sensor to improve the hydration of sample (as Charlton does suggest), then it would follow that it would have been obvious to add this same polymer to the conductive ink when the conductive ink contains the sensing layer components as well because the addition of the hydrophilic polymer ensures that the enzyme in the conductive ink would also be suitably hydrated with blood sample.

40. Applicant urges that if Say and Charlton were to be combined properly, the teaching of Charlton would result in a sensor described by Say with a layer of hydrophilic polymer deposited over the surface of the electrode. However, as the examiner discussed above, Charlton teaches that this hydrophilic agent (i.e. polymer) could be incorporated into the chemistry layer (col. 4, ll. 10 and 11) and the chemistry layer of Say in the embodiment of col. 20 is in the conductive ink. Moreover, it is unclear why applicant believes one combining Say and Charlton would do so in the argued manner as such a combination would appear to go against what Charlton actually

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desires. In particular, Charlton teaches that the polymer should be combined with the enzyme or the chemistry layer to improve the hydration or wicking of the enzyme or chemistry layer. If one placed a hydrophilic polymer over the conductive track of Say as applicant urges, then the enzyme would not be combined with the actual enzyme in the conductive track in contrast to the suggestions of Charlton. Moreover, because the carbon ink of Say is made of graphite (col. 9, ll. 32-36), which is a known hydrophobic substance, the fluid would only wick to the hydrophilic polymer layer above the location of the enzyme and mediator and wouldn't facilitate the hydration of the actual enzyme itself. This would thereby defeat the purpose the hydrophilic polymer of Charlton even served.

41. Applicant further urges that the incorporation of the hydrophilic polymer into the conductive ink of the electrode would impair the conductive properties of the electrode. This argument entirely ignores that the primary teaching in this rejection is Say and Say already recognized that a number of agents (enzymes, mediators, binders, etc) can be added to the conductive ink presumably without any fatal effect to the performance of its electrodes. See col. 20, ll. 10-29. Because Say recognized that a number of non-conductive agents can be added to a conductive ink without destroying its sensing properties, one possessing ordinary skill in the art would recognize that adding any additional non-conductive agent, which the examiner would note applicant only adds in a 1% amount in the present invention (p. 20, ll. 25-27), would not destroy the function of the electrode. Moreover, the examiner is confused by the argument that one possessing ordinary skill in the art would not anticipate that incorporating a hydrophilic polymer into a conductive ink would allow the hydrophilic polymer to maintain its properties while also allowing the conductive ink to maintain its properties. A hydrophilic polymer is

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hydrophilic whether it is in a conductive ink or whether it is in a separate layer. The enzymes and mediators of Say were still enzymes and mediators when they were incorporated into the conductive ink (i.e. there was no disclosed loss of function of these elements), so it is unclear why the applicant believes a hydrophilic polymer added to the ink would be any different. As to whether the conductive ink would also remain conductive upon addition of hydrophilic polymer, Say already shows that a number of additional constituents can be added to an ink with the ink still functioning as a conductive material (i.e. as an electrode) (see discussion above), so it is unclear why applicant believes a hydrophilic polymer would be any different. It is further noted that there is very little detail in the present invention concerning the addition of hydrophilic polymer to the conductive ink. In particular, the only discussion the examiner can find for adding hydrophilic polymer to the conductive ink can be found on p. 5, ll. 13-15 and p. 20, ll. 25-27 in the specification and the disclosure gives no indication that this addition of polymer could possibly adversely affect either the polymer performance or the conductive ink performance.

42. Applicant further urges that Charlton's conductive ink is a mixture of carbon and silver to provide a low chemical resistance path for the electrodes. Hence, Charlton teaches away from incorporating additional chemical moieties into its conductive ink. It is entirely unclear what this argument is in reference to as the examiner has never suggested one modify the conductive ink of Charlton. Rather the rejection is based on the fact that it would have been obvious to one of ordinary skill in the art to modify the conductive ink of Say. As discussed above, Say already recognized that a number of additional components can be incorporated into the ink. In a follow up to this argument applicant urges that the examiner must address all of the teachings of Charlton, not just those that are convenient for making the rejection. However, this whole

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argument by the applicant is based on the proposition that one possessing ordinary skill in the art would not modify the ink of Charlton, and examiner never suggested modifying the ink of Charlton. As the examiner noted repeatedly in this discussion, most of the applicant's arguments appear to completely ignore that the primary teaching for incorporating the chemistry components of the sensor into the conductive ink is Say and not Charlton. Charlton is being utilized solely for its teaching that it was known to incorporate hydrophilic polymer into an enzyme or chemistry layer of a sensor to improve the hydration of the enzyme. Hence, it is unclear what portion of Charlton the applicant believes the examiner is ignoring.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAJ K. OLSEN whose telephone number is (571)272-1344. The examiner can normally be reached on M-F 5:30-2:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam X. Nguyen can be reached on 571-272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kaj K Olsen/
Primary Examiner, Art Unit 1795
January 30, 2009